UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION **This Document Relates to All Actions**	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge Oral Argument Requested

DEFENDANTS' MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS' MOTION TO PRECLUDE OPINIONS OF DEFENSE EXPERT JOHN M. FLACK, M.D.

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Pursuant to Federal Rules of Evidence 104, 403, and 702, Defendants' Executive Committee, on behalf of all Defendants in this litigation, submit this memorandum of law in opposition to Plaintiffs' *Daubert* Motion to Exclude Testimony of John M. Flack, M.D.[1] and state as follows:

INTRODUCTION

Dr. Flack has opined, based on his review of the relevant scientific literature, his education and training in epidemiology and internal medicine, and his decades of clinical experience treating hypertension patients, that there is insufficient scientific evidence to establish a general causal relationship between the NDMA and NDEA detected in valsartan and the development of cancer.[2] Dr. Flack is well-qualified to offer these opinions based on his expertise researching and treating hypertension. He employed the same methods and principles he uses in his daily clinical practice to arrive at his conclusions, and these methods and principles are reliable and well-supported. Moreover, his opinions will assist the finder of fact in determining whether there is a general causal link between the nitrosamines found in valsartan and the development of the cancers at issue. Accordingly, under the criteria of qualification, reliability, and fit, Dr. Flack's opinions are admissible.

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[1] *See* Ex. A ("Flack Report" or "Flack Rep.").

[2] As Dr. Flack testified during his deposition, *see* Ex. B ("Flack Dep.") at 188:2-11, his opinions apply to all Defendants.

Plaintiffs' Motion should be denied because it stems from a misguided attack on Dr. Flack's relevant qualifications and experience, unwarranted criticisms of his methods, and mischaracterization of his testimony. Emblematic of Plaintiffs' misleading approach is the Motion's false assertion (underlined, no less) that Dr. Flack made an "admission" that "his Report in this case would be 'blasted' in academia for its grave methodological shortcomings." *See* Motion at 1. Dr. Flack made no such "admission"; to the contrary, he successfully countered every attempt by Plaintiffs' counsel to put words in his mouth and consistently defended his methodology and conclusions against Plaintiffs' misdirected criticisms. Each of Plaintiffs' volleys against Dr. Flack falls well short of the mark.

First, Dr. Flack is qualified to offer the opinions he gives on general causation in the context of hypertension, the increased incidence of cancer in patients with hypertension, and whether the medical literature supports an association between the level of NDMA or NDEA in valsartan and cancer in humans. Plaintiffs' challenge that Dr. Flack is unqualified because he is not an oncologist or toxicologist ignores the fact that Dr. Flack is offering opinions regarding general causation as it pertains to hypertension patients, for which he is well-qualified given his decades of experience treating patients with hypertension in his clinical practice.

Second, Plaintiffs' criticisms of Dr. Flack's literature search and his supposed failure to analyze or consider categories of putatively relevant scientific literature

simply ignore the scope of the general causation investigation he undertook and the well-grounded opinions he gives based on that investigation. Plaintiffs criticize Dr. Flack, for example, for purportedly failing to consider dietary studies unrelated to his general causation opinions. But Dr. Flack's inquiry was into the question of *valsartan patients'* potential exposure to NDMA or NDEA and any associated risk of cancer, and he undertook an appropriate literature search directed to that question. Plaintiffs' attempt to improperly re-frame the scope of Dr. Flack's general causation inquiry as a means to attack Dr. Flack's well-reasoned opinions is unavailing. Dr. Flack employed a reliable methodology to reach his conclusions, as clearly set forth in his deposition, and his opinions fit the case. If Plaintiffs wish to criticize Dr. Flack for not researching a different question more to their liking, that is at best a matter of weight, not admissibility, and they can explore the topic through cross-examination.

With respect to the literature Dr. Flack reviewed, he did not simply collect studies based on one database search as Plaintiffs assert. Dr. Flack testified that the materials he considered came from several sources, including not just his search of PubMed (which Plaintiffs emphasize to the exclusion of all other sources), but also materials cited by Plaintiffs' experts and other defense experts, literature cited in the bibliographies of various articles, and documents and articles received from counsel. *See* Flack Report at Ex. B (List of Materials Considered). And Dr. Flack's search of

PubMed—a search engine maintained by the U.S. National Library of Medicine at the National Institutes of Health, with access to more than 33 million references and multiple databases—was adequately calibrated to ensure that Dr. Flack obtained all literature relevant to his inquiry. Plaintiffs' insinuation that Dr. Flack has a different standard for his publication-oriented literature searches and the searches he performed in this case is simply false and misrepresents Dr. Flack's clear testimony explaining his methodology and research. The data Dr. Flack considered was not "cherry-picked," as Plaintiffs repeatedly suggest (Motion at 1, 4, 7, 9-12); his search was comprehensive to his inquiry.

Third, Dr. Flack properly analyzed the literature he reviewed and applied sound scientific methodology and his extensive experience with the comorbidities and cancer risk factors present in the hypertensive patient population in reaching his opinions. Plaintiffs' criticisms of Dr. Flack's methodology ignore his decades of clinical experience practicing internal medicine and treating hypertension patients like Plaintiffs. As a medical doctor, Dr. Flack regularly researches, reviews, and analyzes medical literature in his clinical practice (as well as in his role as a journal editor), to form conclusions on the safety of drugs based on medical literature in treating his patients. He employed the same methodology here.

Plaintiffs' assertion that Dr. Flack was required to conduct a weight of the evidence/Bradford Hill analysis is thus inaccurate. Federal courts have recognized

that physicians who prescribe the drug at issue in a litigation may base their opinions of the drug's safety on their clinical experience and a review of epidemiological studies, because physicians regularly review epidemiological studies to inform their decisions on whether to prescribe the drug to their patients. As an internal medicine physician specializing in hypertension, Dr. Flack is permitted to opine on whether the literature establishes an association between valsartan and cancer based on the literature review he performed. Dr. Flack relied on his education, training, and experience not just in the field of epidemiology but also as a physician to assess the relevant literature and reach well-reasoned conclusions. His methodology satisfies Rule 702 and *Daubert.*

Fourth, contrary to Plaintiffs' mischaracterization, Dr. Flack did not "disavow" any opinions during his deposition. Instead, Plaintiffs have attributed an opinion to Dr. Flack that he never gave apparently for the purpose of excluding it—a pointless exercise.

Plaintiffs have thus identified no valid grounds to exclude Dr. Flack's testimony under Rule 702 or *Daubert*, and the Court should deny Plaintiffs' Motion.

LEGAL STANDARD

Under Rule 702, a witness who is "qualified as an expert by knowledge, skill, experience, training, or education" may offer opinions in a case if (i) the expert's "scientific, technical, or other specialized knowledge will help the trier of fact to

understand the evidence or to determine a fact in issue"; (ii) "the testimony is based on sufficient facts or data"; (iii) "the testimony is the product of reliable principles and methods"; and (iv) "the expert has reliably applied the principles and methods to the facts of the case." *See* Fed. R. Evid. 702. The Third Circuit has explained that Rule 702 "provides for 'a trilogy of restrictions on expert testimony: qualification, reliability, and fit.'" *R.D. v. Shohola, Inc*, 2019 WL 6053223, at *3 (M.D. Pa. Nov. 15, 2019) (quoting *Calhoun v. Yamaha Motor Corp.*, 350 F.3d 316, 321 (3d Cir. 2003)). Under Rule 702, the trial judge acts as a "gatekeeper" to ensure that before it is presented to a jury, expert testimony is "both relevant and reliable." *Id.* (quoting *Buzzerd v. Flagship Carwash of Port St. Lucie, Inc.*, 669 F. Supp. 2d 514, 519 (M.D. Pa. 2009) (citing *Daubert*, 509 U.S. at 589)). In cases where a party objects to the admissibility to proffered expert opinion testimony, the court must examine qualifications, reliability, and fit. *Id.* (citing *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 741-47 (3d Cir. 1994) ("*Paoli II*")). In other words, a qualified expert's "testimony must [(1)] be based on sufficient facts and data; (2) must be the product of a reliable methodology; and (3) must demonstrate a relevant connection between that methodology and the facts of the case." *Id.* (quoting *Jaasma v. Shell Oil Co.*, 412 F.3d 501, 513 (3d Cir. 2005)).

In determining whether proposed testimony is sufficiently reliable, courts are to consider the following factors: (1) whether a method consists of a testable

hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put. *Id.* (citing *In re Paoli R.R. Yard Pcb Litig.*, 35 F.3d 717, 742 n.8 (3d Cir. 1994)).

The requirements of Rule 702 must be applied with the same "'liberal thrust' of the Federal Rules of Evidence and their 'general approach of relaxing the traditional barriers to opinion testimony.'" *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 593 (1993). To be admissible, "the basic minimum is that there must be some scientific validation of the theory advanced by the expert." *Id.* (citing *Daubert*, 509 U.S. at 593); *Holbrook v. Lykes Bros. S.S. Co.*, 80 F.3d 777 (3d Cir. 1996) ("in placing restrictions on [expert's] testimony because he did not possess the exact background the court deemed appropriate, it erred").

Scientific disagreement is not sufficient grounds for the exclusion of expert testimony and is not for the Court to decide in its capacity as a gatekeeper under Rule 702 or *Daubert*. *See, e.g., In re Gabapentin Patent Litig.*, MDL Dkt. No. 1384, 2011 WL 12516763, at *10 (D.N.J. Apr. 8, 2011) (concluding that disagreement between experts regarding application of a methodology presents "a battle of the

experts" to be resolved by the trier of fact); *U.S.* v. *W.R. Grace*, 455 F. Supp. 2d 1196, 1199 (D. Mt. 2006) (Expert testimony even as to disputed evidence is admissible under Rule 702: "It appears that there is some scientific disagreement… It is not the Court's role to settle scientific disputes… [I]t is an issue going to the weight of the evidence, and is best left to the jury"); *see also Broe v. Manns*, No. 15-985, 2016 WL 7048988, at *4 (M.D. Pa. Dec. 5, 2016) ("Any disagreement plaintiffs have with the expert can be dealt with through cross-examination, presentation of contrary evidence and proper jury instructions"); *In re Asbestos Prods. Liab. Litig*., 714 F. Supp. 2d 535, 544 (E.D. Pa. 2010); *In re Diet Drugs Prods. Liab. Litig.,* MDL No. 1203, 2000 WL 962545, at *13 (E.D. Pa. June 28, 2000) (finding that disagreement with the methods used by an expert is a question that "goes more to the weight of the evidence than to reliability for Daubert purposes").

ARGUMENT

I. DR. FLACK IS QUALIFIED TO OFFER HIS GENERAL CAUSATION OPINIONS IN THIS CASE.

Plaintiffs attack Dr. Flack's qualifications on the erroneous basis that he is somehow unqualified by his background as an internal medicine physician, as opposed to an oncologist or toxicologist. *See* Motion at 5. That is a non-issue, as Dr. Flack's qualifications are matched to his opinions. Defendants have offered Dr. Flack as an expert in hypertension. He is not offering toxicology or oncology opinions. His opinions center on hypertension and the relationship between

hypertension and associated risk factors of cancer development. Dr. Flack is indisputably qualified to offer such opinions.

Dr. Flack is President of the American Hypertension Specialist Certification Program, an Associate Editor at the American Journal of Hypertension, and Chair of the American Heart Association (AHA) Hypertension Professional Education and Publications Committee. *See* Flack Report at 3. He is the Professor and Chair of the Department of Internal Medicine at Southern Illinois University (SIU) and the Sergio Rabinovich Endowed Chair of Internal Medicine and Chief of the Hypertension Section in the Division of General Internal Medicine at SIU. *Id.* Dr. Flack has been licensed to practice medicine since 1982 and has lifetime certification as a Specialist in Clinical Hypertension by the American Society of Hypertension. *Id.* at Ex. A, p. 5. He has seen thousands of hypertension patients in his career. *Id.* at 39. His credentials as a hypertension clinician are incontrovertible.

In addition to his background in hypertension, Dr. Flack also has a background in epidemiology. He completed a fellowship on the Epidemiology and Prevention of Cardiovascular disease sponsored by the American Heart Association, holds an MPH from the University of Oklahoma School of Public Health, was a Postdoctoral Research Fellow in Cardiovascular Epidemiology at the National Heart Lung and Blood Institute, Division of Epidemiology at the University of Minnesota School of Public Health, and also holds an MPH in Epidemiology from the University of

Minnesota School of Public Health. *Id*. at 4. Dr. Flack's experience and extensive background at the intersection of hypertension and epidemiology shows his expertise lies squarely in the subject matter on which he opines—the cancer risk factors present in the hypertensive patient population and the causal connection (or absence thereof) between trace amounts of nitrosamines in a hypertension drug and the development of cancer in hypertensive patients to whom the drug is prescribed. He is well qualified to offer the opinions he offers in this case, and Plaintiffs' challenge to his qualifications is groundless.

II. DR. FLACK'S RIGOROUS LITERATURE SEARCH WAS WELL-DESIGNED TO IDENTIFY *RELEVANT* LITERATURE GERMANE TO HIS OPINIONS.

Plaintiffs criticize Dr. Flack's general causation opinions as unreliable because, according to Plaintiffs, Dr. Flack's literature search was informal, non-transparent, non-reproducible, and resulted in cherry-picked evidence. *See* Motion at 9-10. Plaintiffs take specific issue with Dr. Flack's keyword search in the PubMed search engine, focusing on that search to the exclusion of all other elements of Dr. Flack's literature review. *Id.* at 9. At the outset, Plaintiffs unduly and misleadingly minimize the scope of the literature Dr. Flack considered. In addition to his fulsome search of PubMed, Dr. Flack testified that he obtained and reviewed documents and literature from expert witness reports (including experts for both Plaintiffs and Defendants), from the bibliographies of articles that he pulled, and from additional

articles provided by counsel. *See* Flack Dep. at 14:13-15:11. These searches resulted in a robust collection of literature and other materials, largely ignored by Plaintiff's Motion. *See* Flack Report at 5; *id*. at Ex. B. Of note, Plaintiffs cannot point to any literature that is contrary to Dr. Flack's opinions because there is no literature that establishes a causal connection between the NDMA or NDEA in valsartan and cancer or an increased risk of cancer.

Additionally, Plaintiff's disregard the scope of Dr. Flack's general causation investigation and his employment of a literature search appropriate to his inquiry. Dr. Flack's search of PubMed in particular was designed to reveal all studies that addressed NDMA and valsartan; indeed, Plaintiffs acknowledge as much. *See* Motion at 9. As Dr. Flack stated in his report, his task with respect to general causation was analyzing whether the NDMA or NDEA in valsartan could increase the risk of cancer in hypertension patients like the plaintiffs. *See* Flack Report at 2. This is the general causation question before the court and was the particular question underlying his literature search. Accordingly, his keyword search in PubMed for "valsartan" and "NDMA" was properly designed to provide a "neutral snapshot of the existing research *on a particular question*." *See, e.g.*, *In re Zimmer Nexgen Knee Implant Prods. Liab. Litig.*, 2015 WL 5050214, at *3 (N.D. Ill. Aug. 25, 2015) (emphasis added) (denying motion to exclude expert because failure to include certain studies in his review was not the result of biased inclusion or

exclusion criteria designed to provide an inaccurate snapshot of the literature). To the extent Plaintiffs' counsel would have preferred Dr. Flack conduct a literature search on a different topic outside the scope of his general causation investigation, it is unclear why that preference is relevant at all, but at best it goes to weight and is a matter for cross-examination, not exclusion.

Dr. Flack's overall methodology of running neutral search terms on the subject of his inquiry through the PubMed database to obtain a "neutral snapshot" of the relevant literature is well-supported and reliable. PubMed is an online resource for the search and retrieval of biomedical and life sciences literature. *See McBroom v. Ethicon, Inc.*, 2021 WL 2709292, at *3, n.7 (D. Ariz. July 1, 2021). It was developed and is maintained by the National Center for Biotechnology Information at the U.S. National Library of Medicine. *Id.* PubMed provides access to more than 33 million citations for biomedical literature from various sources, including MEDLINE, PubMed Central, journals, and books. *See* National Institutes of Health, *PubMed Overview*, https://pubmed.ncbi.nlm.nih.gov/about/ (last visited on November 29, 2021). As such, Plaintiffs' attempt to relegate PubMed to simply "one database" is misleading. PubMed provides comprehensive access to multiple databases and millions of primary sources.

It is equally misleading for Plaintiffs to assert that Dr. Flack's methodology is deficient here because he purportedly did not follow the identical search criteria

he employed in a past instance when performing a literature search for a specific published study. Indulging in their own cherry-picking exercise, Plaintiffs select one literature search description from just one of Dr. Flack's own publications (out of hundreds of publications in refereed journals) and note that in that particular instance Dr. Flack searched three databases (Medline, PubMed, Cochrane)[3] and employed seven keyword searches. *See* Motion at 8-9. Plaintiffs ignore the reality that the keyword searches Dr. Flack used when conducting that specific literature search were guided by the "particular question" he was researching *in that study*, which happened to be meta-analysis of trials using impedance cardiography in the treatment of adults with hypertension. *See* Flack Dep. 118:18-119:13. As Dr. Flack testified, his procedure for conducting literature searches is to ensure that the *relevant studies* are included. *See* Flack Dep. 122:3-6 ("[What we are] looking for is were [sic] the relevant studies included."); *id*. at 122:17-19 ("You don't include or not include studies based on whether you disagree with the results. You include studies that fit criteria."). This is exactly what Dr. Flack did in this case.

[3]As previously noted, PubMed provides access to more than 33 million citations across multiple databases and sources, including PubMed Central and Medline. Plaintiffs do not explain why searching "numerous databases" yields more rigorous results than searching one comprehensive database with the same content, nor can they identify any relevant study that Dr. Flack would have picked up in Medline or Cochrane that he missed in his PubMed searches.

Moreover, the dietary studies Plaintiffs criticize Dr. Flack for not including simply are not germane to the general causation question he considered, which was whether the NDMA/NDEA to which valsartan patients were exposed increased their risk of cancer. Putting aside the numerous deficiencies of the dietary studies identified by Defendants' other experts, including their failure to account for many confounding factors, at a more basic level, the studies simply did not pertain to Dr. Flack's inquiry because they had nothing to do with NDMA or NDEA in valsartan. As a clinical physician specializing in the treatment of hypertensive patients, Dr. Flack is qualified to review and interpret medical literature pertaining to the drugs he regularly prescribes to opine on their safety. *See* § III, *infra*. That is precisely the methodology he employed here, and dietary studies unrelated to NDMA or NDEA in valsartan were far afield of the general causation question he was tasked with investigating.

Plaintiffs' reliance on *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prods. Liab. Litig.*, 174 F. Supp. 3d 911, 928 (D.S.C. 2016), is misplaced. *See* Motion at 12-13. That case confirms that *relevance* is the cornerstone of a reliable literature search. *See id.* at 929-30 ("A reliable literature review uses formal search methods to allow a researcher to obtain a neutral 'snapshot' of the existing research *on a particular question*. * * * Plaintiffs have made no showing whatsoever that [the expert] performed any search to obtain *relevant literature* . . .

.") (emphasis added, internal citation omitted). Here, Dr. Flack performed a rigorous literature review relevant to the question before him and following the customary standards he uses outside of litigation. He did not fail to account for contrary evidence by omitting dietary studies, because those studies and others outside his search criteria are not contrary to his opinions; they were simply not relevant to the question he was assessing. Indeed, no studies have ever determined that orally ingested NDMA/NDEA increases the risk of cancer in humans, or that the NDMA/NDEA detected in valsartan increases the risk of cancer at all.

III. DR. FLACK USED A RELIABLE CLINICAL METHODOLOGY AND WAS NOT REQUIRED TO PERFORM A BRADFORD HILL ANALYSIS.

Plaintiffs contend that a "weight of the evidence and/or Bradford Hill analysis" is "required" for epidemiological opinions offered in federal courts. *See* Motion at 11. That is an overstatement and is misapplied to Dr. Flack, who has been offered as a clinical expert, not as an epidemiology expert. While it is true that the Bradford Hill analysis has been deemed generally reliable, that does not mean it is the only reliable methodology to introduce expert testimony that includes consideration of epidemiological literature. A standard literature review is also acceptable, particularly when the expert is a medical doctor who regularly prescribes the drug at issue and is offering opinions from a clinical perspective. *See, e.g.*, *In re Yasmin & YAZ (Drospirenone) Mktg., Sales Practices & Products Liab. Litig.*, 2011

WL 6301625, at *7 (S.D. Ill. Dec. 16, 2011); *In re Roundup Prods. Liab. Litig.*, 390 F. Supp. 3d 1102, 1148 (N.D. Cal. July 10, 2018) ("Medical doctors do not need to be epidemiologists in order to testify regarding epidemiological studies, . . . so long as the expert is qualified . . . to interpret these studies and his opinions would be helpful to the jury.") (internal quotation marks omitted).

In *In re Yasmin*, an MDL involving combined hormonal oral contraceptives, Plaintiffs' expert OB/GYN was challenged for offering the opinion that "YAZ and Yasmin are not reasonably safe alternatives to other forms of hormonal contraceptives." 2011 WL 6301625, at *5. In denying defendants' motion to exclude the expert's opinions, the Court noted:

> [The doctor's] method of forming her opinions is reliable as based on epidemiologically based journal articles published in reputable sources . . . . Moreover, her years of education and clinical work provide her with the experience to interpret these articles and studies and explain their findings from the perspective of a practicing OB/GYN, an admittedly different perspective than an epidemiologist. Dr. Bercy-Roberson's method of reading various medical articles and studies to obtain knowledge concerning safety risks of various contraceptives is reliable *as it is the generally accepted method of evaluating the safety risks of various drugs within the medical field.*

Id. at *7 (Emphasis added).

Dr. Flack's methodology fits the same mold. Dr. Flack is Defendants' clinical hypertension expert and is opining on the patient population taking antihypertensive medications. Dr. Flack offers the following general causation opinions:

- The trace amounts of NDMA/NDEA found in valsartan do not independently cause, or increase the risk of, the types of cancers alleged by Plaintiffs;
- No medical professional could credibly claim that Plaintiffs' cancers are caused by their use of valsartan, given the lack of corroboration of independent or augmented cancer risk in large human cohort studies using the same levels of NDMA/NDEA and conducted over a period of time similar to Plaintiffs' exposure;
- No medical professional could credibly claim that any Plaintiff would not have developed cancer had they not taken valsartan; and
- Hypertensive patients carry a higher incidence of cancer risk than the general population, and typically have comorbidities that are risk factors for various cancers.

See Flack Report at 41. Dr. Flack's opinions are based on his knowledge and experience in treating thousands of hypertension patients along with the materials he considered and cited in his report. *See* Flack Dep. at 186:13-20. The testimony cited by Plaintiffs also supports this. *See id*. at 187:2-6 ("Section IX was written before the report was sent, anything that is needed to be referenced is referenced in there, so there is nothing that's come up beyond that.").

Dr. Flack thus bases his opinions on his education, training, and experience, along with his assessment of the relevant literature. *See* Flack Report at 31. The fact that Dr. Flack's opinions derive from his review of epidemiology studies as well as his clinical experience does not mean that he needed to complete a full Bradford Hill analysis. As a medical doctor who regularly prescribes valsartan, his review of medical literature to obtain information about the safety of drugs that he prescribes is part and parcel of his practice. Dr. Flack is permitted to opine on whether the medical literature establishes any enhanced risk of cancer development in hypertension patients based on a literature review, in light of his experience as a medical doctor and practicing clinician with decades of experience treating thousands of hypertensive patients.

IV. DR. FLACK DID NOT RETRACT OR DISAVOW ANY OPINION DURING HIS DEPOSITION.

Plaintiffs' final challenge to Dr. Flack misstates his testimony to assert, wrongly, that he retracted opinions when he did not. Dr. Flack opined in his Report: "When the valsartan recalls occurred, physicians, including myself, had to find alternative treatment options for patients previously prescribed valsartan. In my personal experience, I did not witness any patients have an adverse effect as a result of the NDMA/NDEA impurities found in valsartan." Flack Report at 30. Plaintiffs seek to exclude this opinion on the grounds that Dr. Flack purportedly "retracted" and "expressly disavowed" the opinion during his deposition. Motion at 13-15. He

did not. When asked about the sentence, Dr. Flack explained that "adverse effect" does not mean cancer, and that he just meant his patients were able to transition from valsartan to alternative therapies with "zero problem[.]" Flack Dep. at 177:14-179:3.

Dr. Flack has neither "retracted" nor "disavowed" this opinion. Plaintiffs even concede they are not seeking to exclude the opinion he actually gave. *See* Motion at 15 ("Plaintiffs do not seek to exclude Dr. Flack's observation that he did not witness any patients have difficulty finding appropriate alternative hypertension therapies."). It seems Plaintiffs are instead attempting to exclude an opinion Dr. Flack never offered "[t]o the extent" it might be construed as an opinion about the lack of a cancer diagnosis among patients who took recalled valsartan. Motion at 15. In short, Plaintiffs are ascribing an opinion to Dr. Flack that he never gave for purposes of excluding it. That is not the point of Rule 702, which is directed to an expert's actual opinions, not conjecture about opinions never offered. *See* Fed. R. Evid. 702.

To be clear, Dr. Flack has clearly and unambiguously offered his general causation opinions that the NDMA or NDEA found in valsartan does not independently cause or increase the risk of the types of cancers alleged by Plaintiffs, and no medical professional could credibly claim otherwise. *See* Flack Report at 41. He bases these opinions on his training, education, experience, and literature review. *See id*. at 31. Plaintiffs have failed to offer any valid basis under *Daubert* or Rule 702 for the exclusion of these central general causation opinions. Plaintiffs'

speculative efforts to exclude other opinions Dr. Flack has not offered merely reinforce that Dr. Flack's actual general causation opinions are qualified, reliable, and fit the general causation question before this Court.

CONCLUSION

Based on the above-cited authority and for the foregoing reasons, Defendants respectfully request that the Court deny Plaintiffs' Motion. Dr. Flack is qualified to offer his opinions in this case. Moreover, Dr. Flack's literature search and review are methodologically sound. Plaintiffs' criticisms of Dr. Flack's methodology are largely the result of an improper framing of his general causation inquiry and a mischaracterization of his methodology and testimony. Plaintiffs have failed to point to any valid ground to exclude Dr. Flack's opinions, and their Motion should accordingly be denied.

Dated: December 1, 2021

Respectfully Submitted by the Defense Executive Committee on behalf of all Defendants,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on December 1, 2021, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send a notice of electronic filing to all CM/ECF participants in this matter.

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